

# PATENT COOPERATION TREATY

Rec'd PCT/PTO 17 DEC 2004

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

<b>To:</b> GIDDINGS, Peter J GLAXOSMITHKLINE CIP (CN925.1) 980 Great West Road Brentford Middlesex, TW8 9GS GRANDE BRETAGNE		GlaxoSmithKline Corporate IP 01 JUL 2004 Received NESP GlaxoSmithKline Corporate IP Received BRENTFORD 30 JUL 2004		<b>NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT</b> (PCT Rule 71.1)	
		Date of mailing (day/month/year)		28.06.2004	
Applicant's or agent's file reference JNR/PB60210		ATTN: J.S. / ADMIN: J.S. PM N/A OR UPDATED ON:		<b>IMPORTANT NOTIFICATION</b>	
International application No. PCT/EP 03/06466		International filing date (day/month/year) 19.06.2003		Priority date (day/month/year) 21.06.2002	
Applicant GLAXO GROUP LIMITED et al.					

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**


The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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 Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>JNR/PB60210</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. <b>PCT/EP 03/06466</b>	International filing date ( <i>day/month/year</i> ) <b>19.06.2003</b>	Priority date ( <i>day/month/year</i> ) <b>21.06.2002</b>
International Patent Classification (IPC) or both national classification and IPC <b>G06M1/04</b>		
Applicant <b>GLAXO GROUP LIMITED et al.</b>		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	<p>This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of    sheets.</p>

3.	<p>This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I    <input checked="" type="checkbox"/> Basis of the opinion</li> <li>II   <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input checked="" type="checkbox"/> Lack of unity of invention</li> <li>V   <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>
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Date of submission of the demand  <b>12.12.2003</b>	Date of completion of this report  <b>28.06.2004</b>
Name and mailing address of the international preliminary examining authority:  <div style="display: flex; align-items: center;"> <div>             European Patent Office              D-80298 Munich              Tel. +49 89 2399 - 0 Tx: 523656 epmu d              Fax: +49 89 2399 - 4465           </div> </div>	Authorized Officer  <b>Lacroix, P</b>  Telephone No. +49 89 2399-2707



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 03/06466**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-45 as originally filed

**Claims, Numbers**

1-69 as originally filed

**Drawings, Sheets**

1-20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 63-69

because:

☒ the said international application, or the said claims Nos. 63-69 relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

**INTERNATIONAL PRELIMINARY  
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International application No. **PCT/EP 03/06466**

- ☐ complied with.
- ☐ not complied with for the following reasons:
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☒ all parts.
- ☐ the parts relating to claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	9-14,35-62
	No: Claims	1,2,4-8,15,21
Inventive step (IS)	Yes: Claims	9-14,35-62
	No: Claims	3,16-20,22-34
Industrial applicability (IA)	Yes: Claims	1-62
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 63-69 contain references to the description and/or the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here since the claimed features could already be defined in the claims 1-62.

**Re Item IV**

**Lack of unity of invention**

The separate inventions/groups of invention are: see additional sheet of Box II of the International Search Report.

The separate inventions/groups of invention lack unity since they are not so linked as to form a single general inventive concept (Rule 13.1 PCT).

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1). Reference is made to the following documents:

D1: PATENT ABSTRACTS OF JAPAN vol. 006, no. 195 (P-146), 5 October 1982 (1982-10-05) & JP 57 103585 A (TAMURA ELECTRIC WORKS LTD), 28 June 1982 (1982-06-28)

D2: US 2002/047021 A1 (ENGELBRETH DANIEL K ET AL) 25 April 2002 (2002-04-25)

2). Document D1 discloses an axle (26) of a rotatable element (29, 30, 31, 32) of an actuation indicator (counter), wherein the axle is provided by a spring that is adapted in use to bias the rotatable element towards another element (33,34,35) of the actuation indicator with which the rotatable element is engaged.

Document D2 discloses a casing (Cf. Fig. 6-9 and/or 21-25) adapted to be

attached over a valve stem end (110) of a canister (104) to form a canister unit (17), the casing comprising a sleeve part (120, 1300) having a generally cylindrically shaped section having a generally cylindrical inner surface extending from a top of the sleeve part towards a base wall (150) and a collar (1302) affixable around a neck of said canister, and sized, when around the neck of the canister, to fit through the top of the sleeve part (Cf. Fig. 25) into the sleeve part, whereat it will contact at least a portion of the generally cylindrical inner surface, wherein the generally cylindrical inner surface has a shoulder (304) for supporting the collar to prevent the collar from being inserted further into the sleeve part, the shoulder being spaced from the top and the base wall of the sleeve part, said sleeve part being for receiving a canister, and a cap part (136) for receiving a counter assembly (Cf. [0098] ) of a dose counter for the canister unit, wherein the cap part and counter assembly can be assembled together separate from the sleeve part and canister, the sleeve part and cap part then being joinable together to form the casing and wherein the sleeve part for receiving a valve stem end of a canister is adapted to receive more than one form of valve stem end (Cf. [0134] ).

- 3). The features of the objected dependent claims are either known from D1/D2 or form part of the general knowledge of the person skilled in the art. They do not appear to comprise anything which would go beyond the prior art to an extent that it could be considered as involving an inventive step.

**Certain defects in the international application**

- 4). Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 is not mentioned in the description, nor are these documents identified therein.
- 5). The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate since D1 and/or D2 disclose to a large extent the most of the features implementing the core of the current application.  
The independent claims should therefore be redrafted accordingly.
- 6). The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

**Certain observations on the international application**

- 7). Although claims 15, 21 resp. 35, 59 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought ..and/or.. in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought.

Hence, claims 15, 21 resp. 35, 59 do not meet the requirements of Article 6 PCT. In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of /a single/a minimum number of/ independent claim/claims in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).